UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA v. SB MEDICAL, INC., and TC MEDICAL GROUP, Defendants	Criminal Nos. 1:14-cr-397-1, 2 Hon. Anthony J. Trenga Sentencing Date: 8/7/15

POSITION OF THE UNITED STATES WITH RESPECT TO SENTENCING

Defendants SB Medical, Inc. and TC Medical Group shared a single corporate mission: to make money by circumventing FDA safety regulations. They did this by smuggling misbranded prescription drugs and devices into the country and selling them to U.S. doctors and clinics. These drugs and devices were not approved by the FDA and did not contain the labels, warnings, and instructions required by the FDA. The companies did not have a license to distribute prescription drugs, and did not follow any of the standards one would expect of legitimate drug companies. In total, the Defendants made over **$30 million** in proceeds at the expense of the safety of tens of thousands of unsuspecting patients. Consequently, the Government recommends a fine at the **high-end** of the Guidelines range of $24,258,788.80 to $48,517,577.60, in addition to forfeiture of the proceeds of the crime. Such a fine is necessary to reflect the seriousness of this offense and to deter other companies from entering the lucrative business of smuggling misbranded pharmaceuticals.

I. Offense of Conviction

SB Medical, Inc. and TC Medical Group ("the Defendants") are corporate entities based in Toronto, Canada. They are owned by Reuven and Sophie Lexier, and operated by their son, Tzvi Lexier. The companies shared the same employees, offices, and customers; in fact, the only reason that the Lexiers set-up two companies, instead of one, was to deflect attention from law-enforcement and to allow them to shift assets from one company to the next if necessary.

Between 2011 and 2014, the Defendants generated over $30 million in proceeds by smuggling over twenty types of misbranded prescription drugs and devices into the country. These included drugs like Mabthera, which is used for chemotherapy; drugs like Lucentis, which is used to treat macular degeneration of the eye; and cosmetic drugs like Botox. Most of the drugs and devices the Defendants sold were injectables, meaning they are typically injected into patients with a needle or syringe. Lucentis, for instance, is injected into the patient's eye with a needle.

The Defendants did not have a license to distribute prescription drugs or devices, and ignored basic storage and shipping standards mandated by government regulations and common sense. For instance, the Defendants did not have professional warehouses with temperature or humidity controls. Instead, they stored drugs and devices in their employees' homes, despite safety requirements mandating that the drugs be kept at controlled temperatures. Indeed, the Government has dozens of emails in which the Defendants' top officers and agents showed a blatant disregard for the integrity of the cold-chain[1] drugs and devices they distributed, including:

- On December 12, 2011, defendant Hanoch David Stein informed defendant Tzvi Lexier and an unindicted co-conspirator that Turkish Botox arrived warm. The unindicted co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."
- On February 11, 2014, an unindicted co-conspirator informed defendant Rivka Rabi that a "customer claims that the 3 Prolia they received came warm from the U.K so they want to return it," and then instructed her that "it will go back to you, and we will ship it out as soon as it is cold again."
- On February 19, 2014, defendant David E. Burke emailed defendant Rivka Rabi: "You don't put any ice in the boxes when you ship them to Baltimore right?" The response: "The Botox I do even though it's not sent with ice packs…" Burke replied: "You do not need to put ice in anything going forward."
- On May 28, 2013, a drop shipper in the United States wrote to defendant David Burke and two unindicted co-conspirators: "Don't know if this is a problem but one of the boxes of orencia was wet when I took it out of cooler today." A co-conspirator responded: "please Refrigerate the damaged box of Orencia, but put it separately from the other Orencia. We have one client or two that doesn't mind taking damaged boxes."

The Defendants employed a sales staff based largely in Toronto, Canada. Their job was to trick U.S. doctors and clinics into thinking that the Defendants were American companies, selling FDA-approved products. One of the ways they did that was by using a device called a "MagicJack" that would display a false Baltimore area code on the caller-ID of potential customers. When doctors asked the Defendants' salesmen whether the drugs and devices they sold were FDA-approved, the salesmen were instructed to either dodge the question or provide a misleading answer, such as stating that the drugs were manufactured in an "FDA-

[1] "Cold-chain" products are drugs and devices that must be shipped and stored below room temperature in order to ensure their safety and effectiveness.

approved facility." The Defendants required dishonesty from every member of their sales staff; in fact, according to one witness, the Defendants' head of sales, David Burke, once fired a salesman, telling him bluntly that you are being replaced because "you don't know how to lie."

On May 7, 2015, SB Medical, Inc. and TC Medical Group pled guilty through their agent, Dr. Reuven Lexier, to one count of Conspiracy to Commit Offenses Against the United States – including violations of 18 U.S.C. § 545 (importation contrary to law) and 18 U.S.C. § 331(a) (introducing misbranded drugs and devices in interstate commerce) – in violation of 18 U.S.C. § 371, and one count of Unlicensed Wholesale Distribution of Prescription Drugs, in violation of 21 U.S.C. § 331(t). Both offenses are punishable by a fine of $500,000 or twice the gross gain derived from the offense, whichever is greater, full restitution, five years' probation, and a special assessment.

II. Application of Sentencing Factors

Although the Sentencing Guidelines are advisory, the Court is required to "consult those Guidelines and take them into account when sentencing." *United States v. Booker*, 543 U.S. 220, 264 (2005). A "district court shall first calculate … the range prescribed by the guidelines. Then, the court shall consider that range as well as other relevant factors set forth in the guidelines and those factors set forth in [18 U.S.C.] § 3553(a) before imposing the sentence." *United States v. Hughes*, 401 F.3d 540, 546 (4th Cir. 2005) (citation omitted). The § 3553(a) factors include:

- the nature and circumstances of the offense and the history and characteristics of the defendant;
- the need for the sentence imposed to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; to afford adequate deterrence to criminal conduct; to protect the public from further crimes of the defendant; and to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;
- the kinds of sentences available;
- the kinds of sentence and the sentencing range established for the applicable category of offense committed by the applicable category of defendant as set forth in the guidelines;
- any pertinent policy statement;
- the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and
- the need to provide restitution to any victims of the offense.

Here, two of these factors are particularly relevant: (1) the nature and circumstances of the offense; and (2) the need for the sentence imposed to reflect the seriousness of the offense, promote respect for the law, and afford adequate deterrence to criminal conduct.

A. Nature and Circumstances of the Offense

The Defendants created grave risks to public safety. The drugs and devices they sold are dangerous if not handled, administered, and used correctly. That is why the drugs and devices are highly regulated by the FDA. The FDA must approve any prescription drug or device before it can be sold in the United States. Even when a prescription drug or device is approved, the FDA requires that it contain very specific labels, warnings, and instructions in order to educate doctors about how to administer the drug or device safely and to warn patients about possible side effects. *See* 21 U.S.C. § 355(d) (mandating that the FDA approve new drug applications only if the drug is "safe for use under the conditions prescribed, recommended, or suggested ***in the proposed labeling***") (emphasis added). Drug labeling thus serves as "[t]he centerpiece of [the FDA's] risk management" strategy because it "communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." 71 Fed. Reg. 3934 (2006).

The Defendants' pharmaceuticals did not contain FDA-required labels, and therefore posed serious safety risks. *See* FDA Letter to Doctors about Risks of Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers, http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm ("Medications that are not approved by FDA may lack necessary and required labeling to assure their appropriate and safe use."). Many were missing FDA-mandated "Black-Box Warnings," which are required "in the labeling for medications that have special problems, particularly ones that may lead to death or serious injury." *Id.* Many were also missing FDA-mandated "Medication Guides," which provide information to "help patients avoid serious adverse events." *Id.*

The public health risks created by the Defendants' distribution of misbranded drugs and devices were compounded by the reckless steps they took to cut costs and avoid detection by law enforcement. This includes shipping cold-chain products through circuitous routes and without dry ice, storing products in the messy private residences of their amateur employees, and maintaining little oversight of their convoluted supply-chain. As the FDA has cautioned, such illicit distribution networks pose "a number of potential risks" to patients. *See* Senate Committee on Health, Education, Labor and Pensions, Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA (May 20, 2004) ("*Taylor Testimony*"), http://www.fda.gov/NewsEvents/Testimony/ucm113825.htm. These risks include receiving drugs and devices of uncertain foreign origin that may be "expired, subpotent, contaminated or counterfeit." *Id.* These risks were surely present in this case given the Defendants' cavalier attitude towards the shipping and storage of their products. Indeed, the Government has confirmed that a sample of purported Botox recovered from David Stein's home was counterfeit.

Because of the Defendants' actions, thousands of patients were injected with misbranded and mishandled drugs and devices without their knowledge or consent. As the FDA has warned, "[w]hen consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause." *Taylor Testimony*. Again, these risks appear to have come to fruition in this case, as at least one doctor complained to Defendants that their products caused side effects in five of ten patients, necessitating emergency room visits. *See* TC Medical PSR ¶ 32. And the government may never know whether patients died, or had their illnesses prolonged and recoveries delayed, because they did not receive the full strength of the drugs or devices that the Defendants sold.

B. The Need for the Sentence To Reflect the Seriousness of the Offense, Promote Respect for the Law and Afford Adequate Deterrence

Unfortunately, many individuals and companies are perfectly willing to do what the Defendants did for a chance to make the massive proceeds the Defendants made. As the FDA has told Congress, the task of combating the flow of misbranded pharmaceuticals into this country is "daunting": "Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process." *Taylor Testimony*. As a result of smugglers like the Defendants who intentionally break up large shipments of drugs and devices into many small shipments, the system is "overwhelmed by the number of incoming packages" of unapproved pharmaceuticals, which can number in the hundreds at a single port-of-entry on a single day. *Id.*

Smuggling of misbranded pharmaceuticals into this country has boomed because the leaders of that illegal business have made a calculated choice that the rewards greatly outweigh the risk. Unlike many criminals, those engaged in the distribution of misbranded pharmaceuticals are often sophisticated actors. The Defendants' owner, for instance, is a medical doctor, PSR ¶ 3, and many of their key employees were college graduates. The Defendants went to great lengths to make their illicit business difficult to detect, investigate, and prosecute. This included locating their business outside of the United States, employing false names and addresses, and adopting convoluted shipping and banking practices. Consequently, the Defendants believed that their chance of facing American law enforcement was low, and that the consequences if caught were relatively minor compared to the enormous amount of money to be made.

The money to be made from flouting FDA regulations is not going to decrease, nor will the resources that it takes to investigate and prosecute sophisticated smuggling networks like the one operated by the Defendants. The only way to change the cost-benefit analysis for this crime is to impose meaningful penalties on those who are convicted. If this Court does so, there is every reason to believe that would-be smugglers will get the message. *See United States v. Martin*, 455 F.3d 1227, 1240 (11th Cir. 2006) ("Because economic and fraud-based crime are more rational, cool, and calculated than sudden crimes of passion or opportunity, these crimes are prime candidates for general deterrence."). Just as importantly, a large fine—one that exceeds the proceeds made from this offense—will adequately "reflect the seriousness of the offense" and "promote respect for the law." 18 U.S.C. § 3553(a).

III. Conclusion

The smuggling and distribution of misbranded pharmaceuticals conducted by unlicensed and unscrupulous entities, the Defendants, is a serious and widespread problem. Because these crimes are calculated and pre-meditated, their investigation and prosecution is resource-intensive and difficult. Thankfully, the same sophistication that makes these criminals hard to catch also makes them easy to deter. A meaningful sentence for the Defendants will send a message that is likely to be heard by smugglers around the world who would otherwise be willing to endanger untold numbers of American patients for the chance to make the lavish proceeds received by the Defendants.

Respectfully submitted,

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Date: July 31, 2015

Certificate of Service

I hereby certify that on July 31, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of filing (NEF) to counsel of record for the defense.

I also certify that on July 31, 2014, I will send a true and correct copy of the foregoing by e-mail to the following:

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